MEMORANDUM OF LAW

EXHIBIT A

DECLARATION OF STANLEY H. KREMEN

IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

Stanley H. Kremen,
Attorney at Law
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(732) 593-7294
Attorney for the Plaintiff

Keith Altman
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38228 West 12 Mile Road, Suite 375
Farmington Hills, Michigan 48334
(248) 987-8929
Attorney for the Plaintiff

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

CIVIL ACTION No. 2:21-cv-10312-SJM-RSW

DECLARATION OF STANLEY H. KREMEN IN SUPPORT OF PLAINTIFF'S MOTION FOR LEAVE TO FILE AMENDED COMPLAINT

I, Stanley H. Kremen, being of full age, hereby depose and say under pains and penalties of perjury under the laws of the United States and the State of Michigan:

1. I am an attorney licensed in the State of California and admitted to practice in Federal Court in the Eastern District of Michigan.

2. I represent the Plaintiff, Trutek Corp. ("TRUTEK") in the above captioned matter, and I am their Counsel of Record.
3. On February 10, 2021, I caused a complaint ("Initial Complaint") to be filed against the Defendant, BlueWillow Biologics, Inc. ("BLUEWILLOW"), in the Eastern District of Michigan, Southern Division (ECF No. 1).
4. The Initial Complaint alleged a single count of infringement of TRUTEK's United States Patent No. 8,163,802 ("the '802 Patent") for manufacturing and selling one or more over-the-counter pharmaceutical products named Nanobio® Protect ("NANOBIO").
5. Claims 1 and 2 of the '802 Patent recite a method and a formulation, respectively, to be administered nasally, which exhibits an electrostatic charge, and which contains a cationic agent and a biocidic agent. Cationic agents exhibit a positive electrostatic charge, and biocidic agents destroy microorganisms. Biocidic agents are used in preservatives. Claim 6 of the '802 Patent recites that the cationic agent is benzalkonium chloride, and claim 7 recites that the biocidic agent is benzalkonium chloride.
6. According to information provided by BLUEWILLOW's website (*www.bluewillow.com*) at the time this action was filed, the NANOBIO product exhibits an electrostatic charge, and contains benzalkonium chloride (abbreviated as "BZK" on the BLUEWILLOW website). (*See* Initial Complaint - Exhibit 1 [ECF No. 1-1.].) This revelation by BLUEWILLOW led to TRUTEK's allegation of patent infringement in the sole count of the Initial Complaint.
7. According to information and belief, at some time after the Initial Complaint was filed, BLUEWILLOW ceased manufacturing and selling the NANOBIO product. The NANOBIO product had been previously advertised on BLUEWILLOW's website. (*See* Initial Complaint - Exhibit 1.)
8. According to information and belief, after BLUEWILLOW ceased selling the

NANOBIO product, it removed references to that product.

9. On page 3 of 7 of said Exhibit 1, the website text stated, "[t]he unique effectiveness of Nanobio® Protectis [*sic.*] derived from BlueWillow's patented technology." However, no patent numbers were marked on the NANOBIO product packaging or on the product itself.

10. A search performed by me on the website (*www.uspto.gov*) of the United States Patent and Trademark Office ("USPTO"), done subsequent to filing the Initial Complaint, yielded no patents that are assigned to BLUEWILLOW. However, further research yielded a series of United States patents that are assigned to Nanobio Corporation. The search also yielded published United States patent applications that were assigned to Nanobio Corporation, but which did not mature into patents for one reason or another. According to information and belief, BLUEWILLOW is a successor business entity of Nanobio Corporation.

11. Recognizing the names of some of the inventors listed on the patents owned by Nanobio Corporation, I then searched the USPTO website and found other United States patents listing some of the same inventors. These were assigned to the Regents of the University of Michigan. According to information and belief, some of said inventors migrated from research positions at the University of Michigan to Nanobio Corporation. According to further information and belief, at least two of said inventors occupy executive positions at BLUEWILLOW.

12. Further research revealed articles published in scientific journals, which were written by said inventors.

13. All of the newly discovered patents, patent applications, and scientific articles disclose vaccines for prevention and treatment of various diseases and conditions. These vaccines are contained in nanoemulsion adjuvants, and they are intended for nasal administration to subjects.

14. By their very nature, nanoemulsions consist of extremely small nanoscale liquid

droplets. These droplets exhibit electrostatic charges that cause the droplets to repel one another. If this were not so, the droplets would coalesce into a single coherent liquid.

15. The various patents, patent applications, and scientific articles further disclose that the vaccines contain cationic agents and biocidic agents.

16. Excerpts from the current BLUEWILLOW website (*www.bluewillow.com*) disclose that BLUEWILLOW is currently manufacturing and testing vaccines contained in nanoemulsion adjuvants, which are intended for nasal administration. A copy of excerpts from said website is appended as an exhibit hereto.

17. It is my current good faith belief that BLUEWILLOW's activities, regarding one or more of its vaccines, infringe upon at least claims 1 and 2 of the '802 Patent.

18. When the Initial Complaint was filed, it was TRUTEK's good faith belief that BLUEWILLOW's infringement activities were confined to the NANOBIO product. Only after filing the Initial Complaint did TRUTEK suspect that BLUEWILLOW'S infringement activities extended to their vaccines. The Initial Complaint did not allege that BLUEWILLOW's vaccine activities infringed the claims of the '802 Patent because TRUTEK was unaware of the nexus between the NANOBIO product and the BLUEWILLOW vaccines. The connection was discovered only following extensive research performed following filing of the Initial Complaint.

19. Subsequent to filing this lawsuit, I inquired of BLUEWILLOW's Counsel requesting information regarding the BLUEWILLOW vaccines. I was told that the vaccines are "off limits," because they are protected by the safe harbor of the Hatch Waxman Act. I was told that BLUEWILLOW will resist TRUTEK's discovery efforts regarding its vaccines.

20. On May 2, 2022, BLUEWILLOW responded to TRUTEK's first requests for admissions. In their response, BLUEWILLOW indeed objected to TRUTEK's

requests for discovery regarding their vaccines claiming (1) that they are exempt from infringement allegations because they are protected by the Hatch Waxman safe harbor; and (2) that they are not at issue in this case.

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I declare that the statements made by me above are true and that the exhibit attached hereto is genuine and is correctly described above. I understand that I am subject to the penalties of perjury for false representations according to the laws of the United States and the State of Michigan.

Dated: ___May 2, 2022____

s/ Stanley H. Kremen____

Stanley H. Kremen
Attorney for Plaintiff, Trutek Corp.

EXHIBIT

EXCERPTS FROM BLUEWILLOW WEBSITE

(*www.bluewillow.com*)

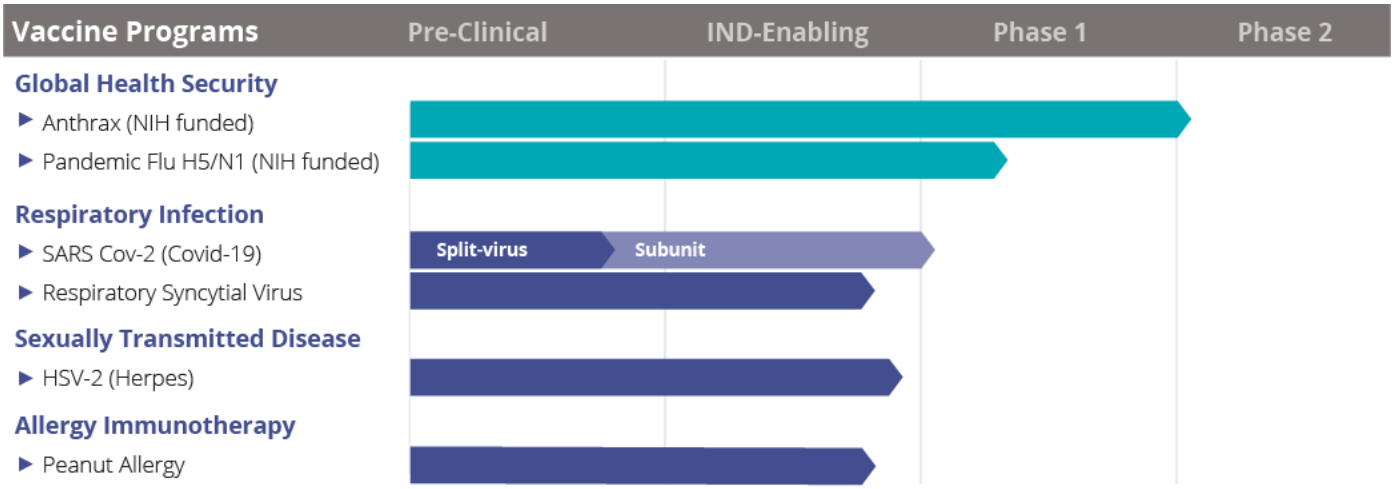
BlueWillow Biologics® is developing and enabling a new generation of safe and effective nasal vaccines and immunotherapy to protect global populations from respiratory infections, sexually transmitted diseases, and food allergies. Our novel intranasal NanoVax® adjuvant platform activates mucosal immunity, the body's first line of defense, while also inducing systemic immunity. We are a clinical-stage company advancing a pipeline of proprietary programs including Peanut Allergy, HSV-2, Covid-19, Anthrax, Pandemic Flu and RSV.

Vaccine Pipeline

BlueWillow's intranasal vaccine platform has successfully demonstrated safety and immunogenicity in humans as well as safety and efficacy in primary animal models for several diseases. A successful phase 1 clinical trial in Anthrax was recently completed. Clinical trials for an intranasal Covid-19 booster as well as therapeutic HSV-2 and pandemic flu vaccines are planned for the near future.

The company has also demonstrated that its adjuvant technology platform shifts the immune response in food allergy from inflammatory (Th2) to protective (Th1) enabling a durable, intranasal immunotherapy candidate. GMP manufacturing of clinical materials is ongoing for the lead Peanut Allergy program leading to near-term clinical development.

BlueWillow Biologics: Vaccine Development Pipeline



BlueWillow Biologics
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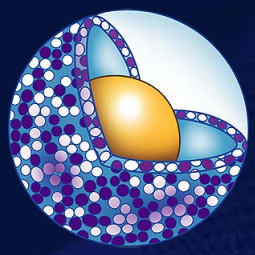
Our Proprietary Technology Platform



BlueWillow's NanoVax® technology platform utilizes a novel oil-in-water nanoemulsion (NE) adjuvant to enable intranasal vaccines for challenging diseases and intranasal immunotherapy (INIT) for food allergies.

JUMP TO: How Do Intranasal NE Vaccines Work?

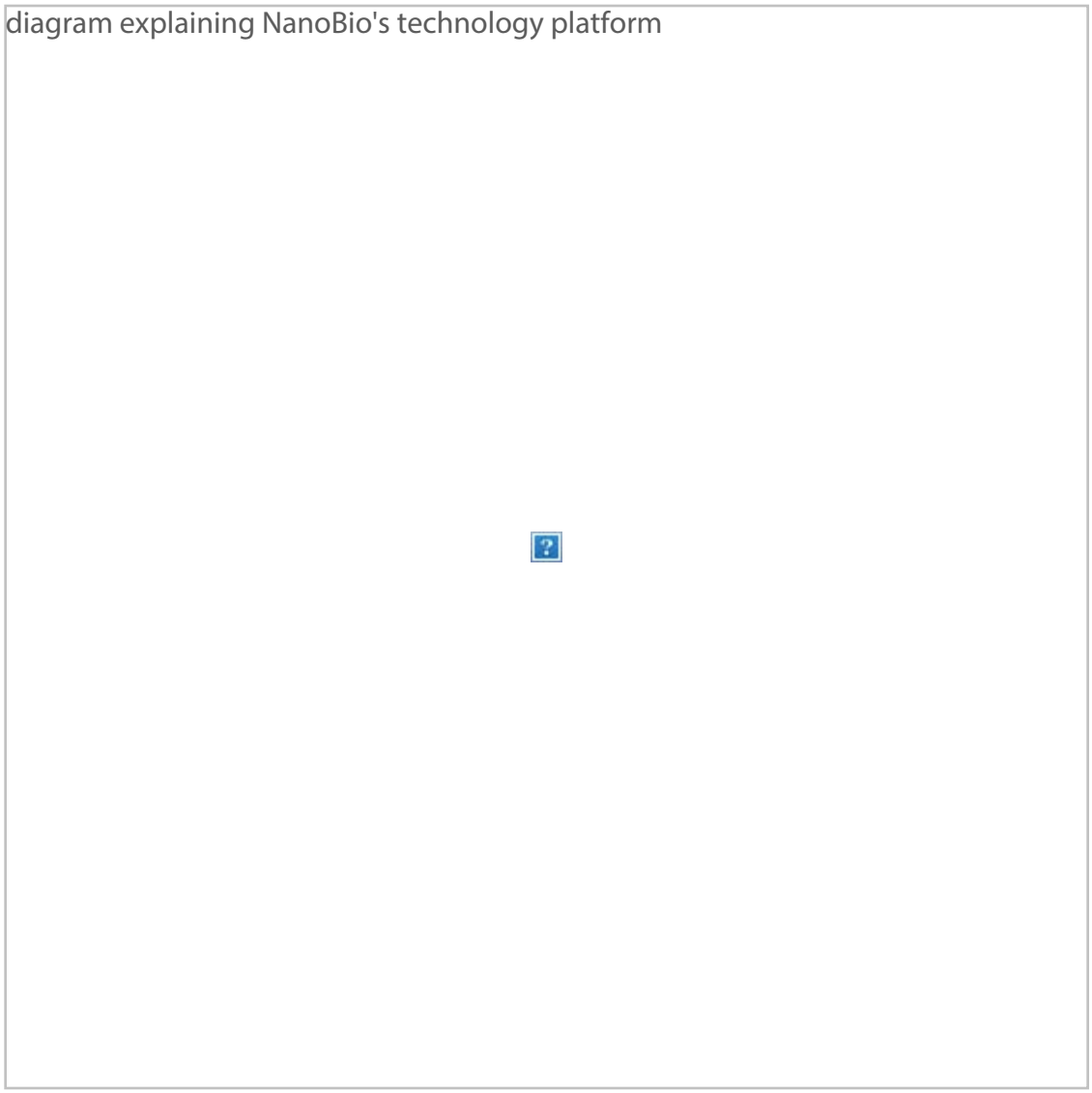
About Our NanoVax® NE01 Adjuvant Technology

BlueWillow's vaccine technology incorporates proprietary oil-in water droplets that are 400–500 nanometers in size to deliver and adjuvant a broad spectrum of vaccines. The NE adjuvant:

- Has established safety and immunogenicity in human clinical trials and efficacy in primary and relevant animal models
- Elicits both systemic and mucosal immunity following intranasal vaccination
- Adjuvants multiple antigen types and enables multi-valent vaccines
- Stimulates a protective immune response that is Th1 biased
- Elicits IL17 and IgA for mucosal protection following intranasal administration
- Has inherent antimicrobial activity. NE01 inactivates and splits enveloped viruses while preserving epitopes, making it ideal for preparation and formulating split/inactivated viral vaccines

How Do Intranasal NE Vaccines Work?

NE01 adjuvanted vaccines are applied intranasally. As shown in the figure below, the adjuvant efficiently activates innate immunity and attracts antigen-presenting dendritic cells. Dendritic cells sample the vaccine at the nasal mucosa and carry the antigen to lymph nodes where it is introduced to the immune system. This path of vaccination results in potent systemic and mucosal immune response. Intranasal NE vaccines have been shown to be immunogenic, safe and well tolerated in Phase 1 human clinical trials.



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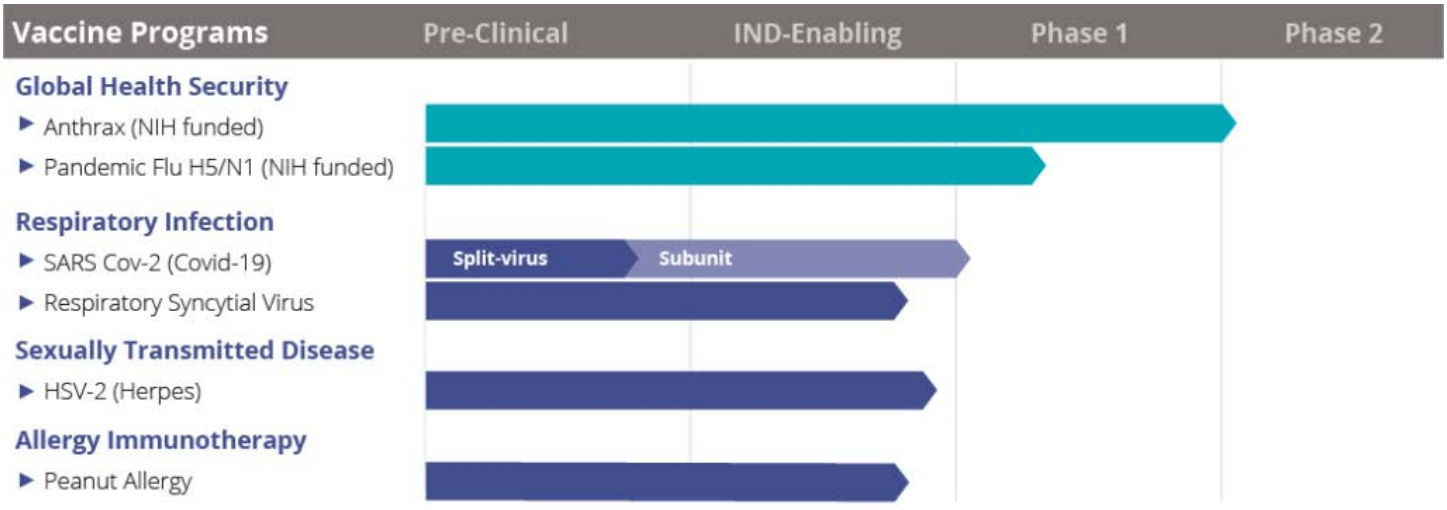
Vaccine Pipeline

BlueWillow's intranasal vaccine platform has successfully demonstrated safety and immunogenicity in humans in addition to safety and efficacy in primary animal models for several diseases. A successful Phase 1 clinical trial for an Anthrax vaccine candidate was recently completed. Clinical trials for an intranasal Covid-19, HSV-2 and pandemic flu vaccines are planned for the near future.

The company has also demonstrated that its adjuvant technology platform shifts the immune response in food allergy from inflammatory (Th2) to protective (Th1) enabling a durable, intranasal immunotherapy candidate. IND-enabling development is being completed for the lead Peanut Allergy program with clinical trials planned for the near future.



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BlueWillow News

March 2, 2022

BlueWillow Announces Promising Results for Intranasal Covid-19 Booster Vaccine

https://www.businesswire.com/news/home/20220302005134/en/BlueWillow-Biologics-and-Medigen-Vaccine-Biologics-Announce-Positive-Results-for-Intranasal-COVID-19-Booster-Candidate-in-Pre-clinical-Studies

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November 3, 2021

BlueWillow Biologics Presents Positive Interim Anthrax Phase 1 Data to BARDA

ANN ARBOR, Mich.–(BUSINESS WIRE)–BlueWillow Biologics, Inc. today announced that the company will present positive interim data from its phase 1 clinical trial of a novel intranasal anthrax vaccine at a Lightning Talks Session of BARDA's Industry Day, November 3 and 4, 2021. BlueWillow's rPA/NE01 anthrax vaccine, BW-1010, developed in collaboration with Porton Biopharma Limited (UK) and […]

September 21, 2021

BlueWillow Biologics Names Leading Viral Infectious Disease Experts to Scientific Advisory Board

BlueWillow Biologics, Inc., a privately held clinical-stage biopharmaceutical company developing intranasal vaccines, today announced the formation of the Company's Scientific Advisory Board (SAB) with three leading viral infectious disease experts. The SAB will provide strategic and scientific counsel to BlueWillow's clinical programs.

August 24, 2021

BlueWillow Biologics Announces Positive Interim Results from Phase 1 Trial of Intranasal Anthrax Vaccine

BlueWillow Biologics, Inc., a privately held clinical-stage biopharmaceutical company developing intranasal vaccines, today announced positive interim results from the Phase 1 clinical trial of BW-1010, its next-generation intranasal anthrax vaccine candidate. BW-1010 combines BlueWillow's patented technology, a novel oil-in-water emulsion platform that efficiently presents antigens to the immune system via the nasal mucosa, with Porton […]

November 10, 2020

Medigen and BlueWillow Biologics Partner to Develop Intranasal Vaccine for SARS-CoV-2

Research indicates that intranasal administration is effective at stimulating the mucosal immunity response. Preclinical study shows positive serum and mucosal immune response. Tapei, Taiwan & ANN ARBOR, Michigan, November 10, 2020 – Medigen Vaccine Biologics Corporation (MVC) (TPEx: 6547.TWO), a biopharmaceutical company focusing on the development and production of vaccines and biologics, and BlueWillow Biologics, […]

October 23, 2019

BlueWillow Receives FDA Clearance to Begin Phase 1 Study of its Intranasal Anthrax Vaccine

BlueWillow Biologics today announced the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug application for the company's next-generation anthrax vaccine candidate. The Phase 1 clinical study is expected to begin enrollment in late 2019.

October 1, 2019

BlueWillow Awarded NIH Contract to Advance Development of its Therapeutic Peanut Allergy Vaccine

BlueWillow Biologics®, a clinical-stage biopharmaceutical company, has been awarded a Fast Track Small Business Research Innovation contract from the National Institute of Allergy and Infectious Diseases for development of an intranasal therapeutic peanut allergy vaccine.

August 6, 2019

BlueWillow Biologics Named to Crain's 'Cool Places to Work in Michigan'

BlueWillow Biologics® today announced the company has been recognized as one of the 2019 "Cool Places to Work in Michigan" by Crain's Detroit.

July 23, 2019

BlueWillow Biologics Awarded Patent for Intranasal Genital Herpes Vaccine

BlueWillow Biologics® today announced the issuance of U.S. patent number 10,206,996 to BlueWillow for the development of an intranasal NanoVax® herpes simplex virus (HSV) vaccine.

May 29, 2019

BlueWillow Biologics Announces Issuance of Intranasal Anthrax Vaccine Patent

BlueWillow Biologics® today announced the issuance of U.S. patent number 10,138,279 covering an intranasal NanoVax® anthrax vaccine.

September 26, 2018

BlueWillow Biologics Awarded Grant for Chlamydia Vaccine Development

BlueWillow Biologics® today announced the company has been awarded an NIH Small Business Innovation Research (SBIR) grant for the development of an intranasal NanoVax® vaccine for the prevention of chlamydia.

May 30, 2018

BlueWillow Biologics Announces Issuance of Therapeutic Cancer

Vaccine Patent

BlueWillow announces the issuance of a patent to the University of Michigan, under exclusive license to BlueWillow, which allows use of BlueWillow's NanoVax® platform with tumor antigens to create novel therapeutic vaccines that could potentially generate immune responses to treat existing cancers.

May 7, 2018

NanoBio Announces Corporate Name Change to BlueWillow Biologics and Closes $10M Series A Financing

NanoBio Corporation, a clinical-stage biopharmaceutical company, today announced that it has changed its corporate name to BlueWillow Biologics® in conjunction with the closing of a $10 million Series A financing. The financing round was led by North Coast Technology Investors, Line Moon Ventures and the University of Michigan through its MINTS initiative.

April 11, 2018

University of Michigan Researchers Show Intranasal NanoVax Vaccination Suppresses Peanut Allergies in Mice

BlueWillow's intranasal NanoVax vaccination protected mice from allergic reactions when exposed to peanut, according to U-M researchers.

June 19, 2017

NanoBio and Porton Biopharma Receive Approval to Advance Next Generation Anthrax Vaccine

NanoBio Corporation today announced the progression of a novel intranasal anthrax vaccine into a pre-clinical IND-enabling toxicology study funded by the U.S. National Institute of Health's National Institute of Allergy and Infectious Diseases (NIAID).

March 6, 2017

NanoBio Receives SBIR Grant For Genital Herpes Vaccine

NanoBio Corporation today announced that it has been awarded a two-year Phase II Small Business Research Innovation (SBIR) grant from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, for the development of an intranasal nanoemulsion (NE) adjuvanted vaccine for the prevention of genital herpes.

December 19, 2016

NanoBio Awarded U.S. Patent for RSV Vaccine

NanoBio Corporation today announced the issuance of a patent which broadly covers the composition of NanoBio's intramuscular and intranasal RSV vaccine candidates, combining the company's innovative nanoemulsion (NE) adjuvant with strain L19 of RSV.

July 27, 2016

NanoBio to Present Intranasal Pertussis Vaccine Data at the Mucosal Immunology Course & Symposium Meeting

NanoBio Corporation today announced that the company will present key data at the Mucosal Immunology Course & Symposium Meeting (MICS) in Toronto, demonstrating the advantages of its intranasal nanoemulsion (NE) adjuvant for use in the development of vaccines for pertussis.

June 2, 2016

NanoBio to Present Data Demonstrating Benefit of Its Intramuscular Nanoemulsion Pandemic Influenza Vaccine

NanoBio Corporation will present key data demonstrating the advantages of its nanoemulsion (NE) adjuvant for use in the development of intramuscular vaccines for pandemic influenza and other diseases,at the GTCbio 14th Vaccines Research & Development Conference on June 3, 2016.

September 22, 2015

NanoBio's Genital Herpes Vaccine Demonstrates Efficacy in Guinea Pigs as Both a Prophylactic and a Therapeutic Vaccine

NanoBio Corporation today announced that its intranasal nanoemulsion (NE) adjuvanted genital herpes vaccine has demonstrated efficacy in studies conducted in both the prophylactic and the therapeutic guinea pig model. The data was recently presented at the 40th Annual International Herpesvirus Workshop in Boise, ID.

BlueWillow Biologics

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Scientific Publications

Intranasal Nanoemulsion Vaccines:

A novel combination of intramuscular vaccine adjuvants, nanoemulsion and CpG produces an effective immune response against influenza A virus. Wang SH, Chen J, Smith D, Cao Z, Acosta H, Fan Y, Ciotti S, Fattom A, Baker JR Jr. *Vaccine*. 2020 Apr 23;38(19):3537-3544.

Intranasal nanoemulsion-adjuvanted HSV-2 subunit vaccine is effective as a prophylactic and therapeutic vaccine using the guinea pig model of genital herpes. Bernstein DI, Cardin RD, Bravo FJ, Hamouda T, Pullum DA, Cohen G, Bitko V, Fattom A. *Vaccine*. 2019 Oct 8;37(43):6470-6477.

A nanoemulsion-adjuvanted intranasal H5N1 influenza vaccine protects ferrets against homologous and heterologous H5N1 lethal challenge. Smith D, Streatfield SJ, Acosta H, Ganesan S, Fattom A. *Vaccine*. 2019 Sep 30;37(42):6162-6170.

Recombinant H5 hemagglutinin adjuvanted with nanoemulsion protects ferrets against pathogenic avian influenza virus challenge. Wang SH, Smith D, Cao Z, Chen J, Acosta H, Chichester JA, Yusibov V, Streatfield SJ, Fattom A, Baker JR Jr. *Vaccine*. 2019 Mar 14;37(12):1591-1600. *Vaccine*. 2019.02.002.

Nanoemulsion Adjuvant–Driven Redirection of TH2 Immunity Inhibits Allergic Reactions in Murine Models of Peanut Allergy. Jessica J. O'Konek, Jeffrey J. Landers, Katarzyna W. Janczak, Rishi R. Goel, Anna M. Mondrusov, Pamela T. Wong, James R. Baker, Jr; *The Journal of Allergy and Clinical Immunology* (2018).

A Novel Nanoemulsion Vaccine Induces Mucosal Interleukin-17 Responses And Confers Protection Upon Mycobacterium Tuberculosis Challenge In Mice. Mushtaq Ahmed, Douglas M. Smith, Tarek Hamouda, Javier Rangel-Moreno, Ali Fattom, Shabaana A. Khader; *Vaccine*, Volume 35 (2017) 4983-4989.

Immunomodulation Of TH2 Biased Immunity With Mucosal Administration Of Nanoemulsion Adjuvant. Anna U. Bielinska, Jessica J. O'Konek, Katarzyna W. Janczak, James R. Baker Jr.; *Vaccine*, Volume 34 (2016) 4017-4024.

Formulation, High Throughput In Vitro Screening and In Vivo Functional Characterization of Nanoemulsion-Based Intranasal Vaccine Adjuvants. Pamela T. Wong, Pascale R. Leroueil, Douglas M. Smith, Susan Ciotti, Anna U. Bielinska, Katarzyna W. Janczak, Catherine H. Mullen, Jeffrey V. Groom, Erin M. Taylor, Crystal Passmore, Paul E. Makidon, Jessica J. O'Konek, Andrzej Myc, Tarek Hamouda, James R. Baker, Jr.; *PLoS ONE*, May 2015, 10(5): e0126120.

Intranasal Nanoemulsion-Based Inactivated Respiratory Syncytial Virus Vaccines Protect Against Viral Challenge In Cotton Rats. Jessica J O'Konek, Paul E Makidon, Jeffrey J Landers, Zhengyi Cao, Carrie-Anne Malinczak, Jessie Pannu, Jennifer Sun, Vira Bitko, Susan Ciotti, Tarek Hamouda, Zbigniew W Wojcinski, Nicholas W Lukacs, Ali Fattom, and James R Baker, Jr; *Human Vaccines & Immunotherapeutics* 11:12, 2904–2912; December 2015.

Distinct Pathways of Humoral and Cellular Immunity Induced with the Mucosal Administration of a Nanoemulsion Adjuvant. Anna U. Bielinska, Paul E. Makidon, Katarzyna W. Janczak, Luz P. Blanco, Benjamin Swanson, Douglas M. Smith, Tiffany Pham, Zsuzsanna Szabo, Jolanta F. Kukowska-Latallo, and James R. Baker, Jr; *The Journal of Immunology*, 2014, 192: 2722–2733.

Intranasal Immunization With W805EC Adjuvanted Recombinant RSV Rf-Ptn Enhances Clearance Of Respiratory Syncytial Virus In A Mouse Model. Crystal Passmore, Paul E Makidon, Jessica J O'Konek, Joseph A Zahn, Jessie Pannu, Tarek Hamouda, Vira Bitko, Andrzej Myc, Nicolas W Lukacs, Ali Fattom, and James R Baker, Jr; *Human Vaccines & Immunotherapeutics* 10:3, 615–622; March 2014.

Nanoemulsion Nasal Adjuvant W805EC Induces Dendritic Cell Engulfment Of Antigen-Primed Epithelial Cells. Andrzej Myca, Jolanta F. Kukowska-Latalloa, Douglas M. Smith, Crystal Passmore, Tiffany Pham, Pamela Wong, Anna U. Bielinska, James R. Baker Jr.; *Vaccine* 31 (2013) 1072–1079.

Safety and Immunogenicity of a Novel Nanoemulsion Mucosal Adjuvant W805EC Combined with Approved Seasonal Influenza Antigens. L.R. Stanberry, J.K. Simon, C. Johnson, P.L. Robinson, J. Morry, M.R. Flack, S. Gracon, A. Myc, T. Hamouda, J.R. Baker Jr; *Vaccine*, Volume 30, Issue 2, 5 January 2012, Pages 307–316.

Nanoemulsion Mucosal Adjuvant Uniquely Activates Cytokine Production By Nasal Ciliated Epithelium And Induces Dendritic Cell Trafficking. Paul E. Makidon, Igor M. Belyakov, Luz P. Blanco, Katarzyna W. Janczak, Jeffrey Landers, Anna U. Bielinska, Jeffrey V. Groom and James R. Baker Jr.; *European Journal of Immunology*. 2012. 42: 1–14.

Nanoemulsion W805EC Improves Immune Responses Upon Intranasal Delivery Of An Inactivated Pandemic H1N1 Influenza Vaccine. Subash C. Das, Masato Hatta, Peter R. Wilker, Andrzej Myc, Tarek Hamouda, Gabrielle Neumann, James R. Baker Jr., Yoshihiro Kawaoka; *Vaccine* 30 (2012) 6871– 6877.

A Novel Inactivated Intranasal Respiratory Syncytial Virus Vaccine Promotes Viral Clearance without Th2 Associated Vaccine-Enhanced Disease. Dennis M. Lindell, Susan B. Morris, Maria P. White1, Lara E. Kallal, Phillip K. Lundy, Tarek Hamouda, James R. Baker Jr, Nicholas W. Lukacs; *PLoS ONE*, July 2011, Volume 6, Issue 7, e21823.

Intranasal Immunization of Ferrets with Commercial Trivalent Influenza Vaccines Formulated in a Nanoemulsion-Based Adjuvant. Tarek Hamouda, Joyce A. Sutcliffe, Susan Ciotti and James R. Baker, Jr., *Clinical and Vaccine Immunology*, July 2011,p. 1167-1175, Vol. 18, No. 7.

Induction of Th17 Cellular Immunity With a Novel Nanoemulsion Adjuvant. Anna U. Bielinska, Michele Gerber, Luz P. Blanco, Paul E. Makidon, Katarzyna W. Janczak, Michael Beer, Benjamin Swanson, and James R. Baker Jr., *Crit Rev Immunol.* 2010 ; 30(2): 189–199.

Characterization Of Stability And Nasal Delivery Systems For Immunization With Nanoemulsion-Based Vaccines. Makidon PE, Nigavekar SS, Bielinska AU, Mank N, Shetty AM, Suman J, Knowlton J, Myc A, Rook T, Baker JR Jr., *Journal of Aerosol Medicine and Pulmonary Drug Delivery*. Volume 23, Number 2, 2010, pp. 77-89.

Efficacy, Immunogenicity and Stability of a Novel Intranasal Nanoemulsion-Adjuvanted Influenza. Tarek Hamouda, Alexander Chepurnov, Nicholas Mank, Jessica Knowlton, Tatiana Chepurnova, Andrzej Myc, Joyce Sutcliffe and James R. Baker, Jr; *Human Vaccines* 6:7, 1-10; July 2010.

A Novel, Killed-Virus Nasal Vaccinia Virus Vaccine. Ann U Bielinska, Alexander A. chepurnov, Jeffrey J. Landers, Katarzyna W. Janczak, Tatiana S. Chepurnova, Gary D. Luker, and James R. Baker, Jr. *Clinical and Vaccine Immunology*, Feb 2008, p.348-358.

Nasal Immunization with a Recombinant HIV gp120 and Nanoemulsion Adjuvant Produces TH1 Polarized Responses and Neutralizing Antibodies to Primary HIV Type 1 Isolates. Ann U Bielinska, Katarzyna W. Janczak, Jeffrey J. Landers, David C. Montefiori, and James R. Baker, Jr. *AIDS Research and Human Retroviruses*, Volume 24, Number 2, 2008.

Pre-Clinical Evaluation of a Novel Nanoemulsion-Based Hepatitis B Mucosal Vaccine. Paul E. Makidon, Anna U. Bielinska, Shraddha S. Nigavekar, Katarzyna W. Janczak, Jessica Knowlton, Alison J. Scott, Nicholas Mank, Zhengyi Cao, Sivaprakash Rathinavelu, Michael R. Beer, J. Erby Wilkinson, Luz P. Blanco, Jeffrey J. Landers, James R. Baker, Jr.; *PLoS ONE*, 8/2008, Volume 3, Issue 8.

Mucosal Immunization with a Novel Nanoemulsion-Based Recombinant Anthrax Protective Antigen Vaccine Protects against Bacillus anthracis Spore Challenge. Anna U. Bielinska, Katarzyna W. Janczak, Jeffrey J. Landers, Paul Makidon, Laurie E. Sower, Johnny W. Peterson, and James R. Baker, Jr.; *Infection and Immunity*, p. 4020–4029 Vol. 75, No. 8, (2007).

Development of Immune Response that Protects Mice from Viral Pneumonitis after a Single Intranasal Immunization with Influenza A Virus and Nanoemulsion. Myc A, Kukowska-Latallo JF, Bielinska AU, Cao P, Myc PP, Janczak K, Sturm TR, Grabinski MS, Landers JJ, Young K, Chang J, Hamouda T, Olszewski MA, Baker,

Jr JR. *Vaccine*; 21: 3801-3814, (2003).

Prevention of Murine Influenza A Virus Pneumonitis by Surfactant Nanoemulsions. Donovan BW, Reuter JD, Cao Z, Myc A, Johnson KJ, and Baker Jr. *Antiviral Chemistry & Chemotherapy*; 11: 41-49, (2000).

Nanotechnology-Based Dermatology and Anti-infective Applications:

Screening Of Nanoemulsion Formulations And Identification Of NB-201 As An Effective Topical Antimicrobial For Staphylococcus Aureus In A Mouse Model Of Infected Wounds. Yongyi Fan, MS, Susan Ciotti, PhD, Zhengyi Cao, MD, Rone Eisma, MS, James Baker Jr., MD, Su He Wang, MD. *Military Medicine*, 181, 5:259, 2016

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